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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,282

08/22/2006

Eric E. Schadt

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

04/12/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

Office Action Summary	Application No. 10/567,282	Applicant(s) SCHADT ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108-134, 137-139, 142-160, 211-235 and 297-318 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 108-134, 137-139, 142-160, 211-235 and 297-318 is/are rejected.
- 7) ☒ Claim(s) 129, 132, 211 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08222006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election without traverse of Group II (claims 108-134, 137-139, 142-160, 211-235, and 297-318) and cancelled claims 89 and 236, filed 2/16/10, are acknowledged.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, Figure 45A. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks a SEQ ID No cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. (Applicant can amend the specification on page 29 to recite that Fig. 45A and 45B are SEQ ID NO: 23). Applicant(s) are required to submit a new computer readable form sequence listing, and a paper copy, or CD-ROM incorporated by reference into the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

The information disclosure statement, filed 8/22/06, has been considered by the Examiner.

Claims herein under examination are 108-134, 137-139, 142-160, 211-235, and 297-318.

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Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on pages 63, 97, 98, 141, 142, 143, and elsewhere. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 129, 132, and 211 objected to because of the following minor informalities:

Claim 129 fails to end in a period.

Claim 132 (line 7) contains an improper period.

Claim 211 (line 9) contains an improper period.

Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 108-134, 137-139, 142-158, 211-235, and 299-318 are rejected under 35

U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 108-134, 137-139, 142-158, 211-235, and 299-318 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or

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apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. It is noted that the instant claim 1 recites “identifying one or more loci in the genome”; however, this step is not a transformation of an article to a different state or thing. It is further noted that claims 108-134, 137-139, 142-158, 211-235, and 299-318 do not explicitly require that the steps of the claimed method are performed on a machine. Applicant is cautioned against introduction of new matter in an amendment.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 109, 110, 121, 128-134, 137-139, 142-145, 147-148, 152, 154, 156-158, 223, 232, and 307 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The term "associated with" in claims 109, 110, 119, 120, and 304 is a relative term which renders the claim indefinite. The term "associated with" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Clarification of this issue via clearer claim wording is requested. Claims 121, 128-134, 137-139, 142-145, 147-148, and 307 are also rejected due to their dependency from claims 109 and 110.

The equations in 152, 156, and 232 lack clarity. For example, claim 152 recites "+ =" which lacks clarity. Claim 156 recites "Q." which is not present in claim 108 or explained in claim 156 and therefore lacks clarity. Claim 232 recites "+ +" which lacks clarity. Clarification of this issue via clearer claim wording is requested. Claims 154, 157-158 are also rejected due to their dependency from claims 152, 156.

Claim 223 recites the limitation "said at least one organism" in line 2. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of this limitation. Clarification of this issue via clearer claim wording is requested.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 108-134, 137-139, 142-160, 211-235, and 297-318 are rejected under 35 U.S.C. 102(e) as being anticipated by Schadt et al. (US 2006/0111849).

Schadt et al. disclose a method, computer product, and system of determining whether a first trait is causal for a second trait in a plurality of organisms of a species (abstract, 0092, 0248, claim 54) comprising identifying one or more loci that is a site of colocalization for quantitative trait loci for first and second traits (abstract, 0017-0019, 0027, 0086, 0280, 0287, 0388), testing each locus for genetic variation (0003, 0088-0092, 0095, 0127), wherein correlation determines a trait to be causal for a second trait (0018, 0074, 0084-0085, 0093, 0111, 0127, 0242-0249, 0286-0287), as stated in instant claims 108, 159, 160. Schadt et al. disclose determining a QTL using a first and second QTL analysis (abstract), as stated in instant claims 109-110. Schadt et al. disclose colocalization within 1 cM (0285, 0303), as stated in instant claims 111-112, 147-148, 215-216. Schadt et al. disclose a predetermined set of individuals and strains and organisms derived from strains (0037, 0095, 0160, 0318-0319, 0370-0371, 0384) and organisms derived

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from crossing or F2 mating (0034, 0063, claim 11), as stated in instant claims 113-118, 120, 122, 123. Schadt et al. disclose a phenotype associated with human disease, such as obesity, diabetes, etc. (0017, 0024), as stated in instant claims 119-121. Schadt et al. disclose a plurality of one or more organisms (abstract, 0017), as stated in instant claims 124-127, 217-219. Schadt et al. disclose abundance levels of cellular constituents, including RNA (0193, 0197-0200), as stated in instant claims 128, 130, 131, 307, 316. Schadt et al. disclose normalization (claim 12), as stated in instant claim 129. Schadt et al. disclose contacting a gene transcript array with RNA to measure abundance (0193-0200), as stated in instant claim 132. Schadt et al. disclose testing linkage, advancing the position, and repeating steps, and a statistical lod score greater than 4.0 (0022-0023), as stated in instant claims 133-134, 137-139, 142-143. Schadt et al. disclose quantitative measurements that are amounts of concentration of cellular constituents (0319), as stated in instant claims 144-145. Schadt et al. disclose humans (0059), as stated in instant claims 146, 220. Schadt et al. disclose two loci (0075), as stated in instant claim 149. Schadt et al. disclose colocalization and satisfying or failing a pleiotropy test (0085-0088, 0137) and null and alternative hypotheses (0114, 0215, 0255), as stated in instant claims 150-151, 230-231. Schadt et al. disclose the model equations of instant claims 152-154 and 232-234 (0282-0283) and maximum likelihood analysis with by maximizing loglikelihood (0284), as stated in instant claims 155 and 235. Schadt et al. disclose a method, computer product, and system of determining whether a first trait is causal for a second trait in a plurality of organisms of a species (abstract, 0092, 0248, claim 54) comprising identifying one or more loci that is a site of colocalization for quantitative trait loci for first and second traits (abstract, 0017-0019, 0027, 0086, 0280, 0287, 0388), quantifying a first and second coefficients of determination between

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genetic variations (0003, 0080-0092, 0095, 0127), wherein a trait to be causal for a second trait based on the coefficients (0018, 0074, 0080-0085, 0093, 0111, 0127, 0236, 0242-0249, 0286-0287, 0367, 0402-0403), as stated in instant claims 211, 297-298. Schadt et al. disclose using thresholds, including less than 0.10 and less than 0.05 (0087, 0236, Figure 6), as stated in instant claims 212-214. Schadt et al. disclose a complex trait (claim 42), as stated in instant claim 221. Schadt et al. disclose a complex trait that is characterized by an allele that exhibits incomplete penetrance in said species (claim 43) and is a contracted disease (claim 44), as stated in instant claims 222-223, 299-301, 308-309, 310. Schadt et al. disclose the complex trait arises when a gene is mutated (claim 45), simultaneous presence of mutations (claim 46), does not exhibit Mendelian recessive or dominant inheritance (claim 48), is asthma, ataxia telangiectasia, etc. (claim 49), associated with a high frequency of disease-causing alleles (claim 47), colocalize within 40cM, 10cM (claims 50, 52), as stated in instant claims 224-229, 302-306, 311-315. Schadt et al. disclose a first trait is an abundance level with an eQTL and a cQTL (abstract, claim 14), as stated in instant claims 317 and 318.

Thus, Schadt et al. anticipate the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

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1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

April 6, 2010

/Carolyn Smith/
Primary Examiner
AU 1631